NLTSPINE
NonLinear Technologies

510(k) SUMMARY

NLT SPINE's Prow Fusion

Sponsor:

NLT SPINE Ltd.
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Kfar-Saba
Israel 4464103

OCT 16 2013

Contact Person:

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Date Prepared: September 9, 2013

Name of Device: Prow Fusion

Common or Usual Name: Intervertebral body fusion device

Classification Name: Intervertebral body fusion device
21 CFR §880.3080
Product Code MAX

Predicate Devices

NLT Prow Fusion (K112359)

Intended Use / Indications for Use

The Prow-Fusion Intervertebral body fusion device is indicated for spinal fusion procedures at one or two contiguous levels from L2 through S1 in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by the history and radiographic studies. DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. The patient may have had a previous non-fusion spinal surgery at the involved spinal level(s).

The device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (e.g. posterior pedicle screw and rod systems). The device is intended to be used with autogenous bone graft.

Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the Prow Fusion device.

The Prow Fusion intervertebral body fusion device must be inserted using a transforaminal approach.

Purpose of the Special 510(k) notice:

The Prow Fusion is a modification to NLT's previously cleared K112359 Prow Fusion.

Technological Characteristics

The Prow Fusion Intervertbral Body Fusion Device system is comprised of two components. One component is the single-use Prow Fusion implant (intervertebral body fusion device) of various heights and the second component is a set of reusable instruments (the Prow Fusion Delivery System) used for its implantation. The implant is made from PEEK-OPTIMA® LT1 & LT2 and titanium alloy. The implant features 4 PEEK-OPTIMA® LT1 mid segments and titanium end segments. The segments has coarse surface on the superior and inferior surfaces and are attached with titanium pins.

The Prow Fusion intervertebral body fusion implant is inserted using a transforaminal approach. The proximal and the distal segments are bound together by PEEK-OPTIMA® LT2 strip. The PEEK-OPTIMA® LT2 strip is used to pull the distal segment proximally to form a ring-shaped, closed-configuration implant in the disc space.

Performance Data

Performance testing in bench (e.g. Static Compression Test, Static Compressive Shear Test, Static Torsion Test, Dynamic Compression Shear Test, Dynamic Torsion Test, Subsidence Test, Expulsion Test, Dynamic Compression Test, and Particle Analysis Test) per ASTM F2077 and ASTM F2267, demonstrated that the Prow Fusion is substantially equivalent to its predicate Prow Fusion (K112359).

Substantial Equivalence

The Prow Fusion is as safe and effective as its predicate device, Prow Fusion (K112359). The Prow Fusion has substantially similar indications for use and technological characteristics as compared to the predicate device. Any minor differences between the device and predicates do not raise new questions of safety and effectiveness. Further, performance testing has established that the Prow Fusion has equivalent performance and safety as compared to the claimed predicate. Thus, the device is substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 16, 2013

NLT SPINE Limited
% Mr. Jonathan Kahan
Partner
Hogan Lovells US LLP
555 Thirteenth Street, Northwest
Washington, District of Columbia 20004

Re: K130254
Trade/Device Name: Prow Fusion
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: September 16, 2013
Received: September 16, 2013

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin FD Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K130254

Device Name: Prow Fusion

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Prescription Use X AND/OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109) (Per 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices